

IN THE UNITED STATES DISTRICT COURT  
FOR THE MIDDLE DISTRICT OF TENNESSEE  
NASHVILLE DIVISION

IN RE: AREDIA AND ZOMETA )  
PRODUCTS LIABILITY LITIGATION ) NO. 3:06-md-1760  
This Document Relates to Case ) JUDGE CAMPBELL  
No. 3:08-00069 (Forman) )

MEMORANDUM

Pending before the Court is Defendant's Motion for Summary Judgment (Docket No. 2265).  
For the reasons stated herein, Defendant's Motion is GRANTED in part and DENIED in part.

FACTS

Plaintiff Forman brings this action against Novartis alleging that Novartis' drug, Zometa, caused her deceased husband, Mr. Napolitano, to develop osteonecrosis of the jaw ("ONJ"). Plaintiff alleges causes of action for (1) strict liability, (2) negligent manufacture, (3) negligent failure to warn, (4) breach of express warranty, (5) breach of implied warranty, and (6) loss of consortium. Defendant has moved for summary judgment on all claims.

SUMMARY JUDGMENT

Summary judgment "should be rendered if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). In deciding a motion for summary judgment, the Court must review all the evidence, facts and inferences in the light most favorable to the nonmoving party. *Van Gorder v. Grand Trunk Western Railroad, Inc.*, 509 F.3d 265, 268 (6th Cir. 2007). In order to defeat a summary judgment motion, the nonmoving party must provide more than a scintilla of evidence; that is, the nonmoving party must present evidence sufficient to permit a reasonable jury to find in its favor. *Van Gorder*, 509 F.3d at 268.

Entry of summary judgment is appropriate against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's cases, and on which that party will bear the burden of proof at trial. *Id.*

## CAUSATION

Under New York law, which must be applied in this case, the plaintiff must tender evidence in an admissible form demonstrating both general causation and specific causation in a failure to warn products liability case. *Heckstall v. Pincus*, 797 N.Y.S.2d 445, 447 (N.Y. App. Div. 2005). Defendant first contends that Plaintiff's claims must fail because she cannot establish general causation, a required element of all her claims. Defendant bases this argument on its Motion for Summary Judgment Based upon a Failure of General Causation Proof under *Daubert*. The Court has denied that motion and found that there are genuine issues of material fact as to whether Zometa and Aredia generally can cause ONJ.

Next, Defendant argues that Plaintiff cannot prove specific causation; that is, that Zometa proximately caused Mr. Napolitano's ONJ. Defendant has moved to exclude Plaintiff's non-retained specific causation experts, and the Court has not considered the causation testimony of those witnesses. Plaintiff has offered the opinion of a retained expert, however, on specific causation, Dr. Najjar. For purposes of summary judgment, the Court has denied Defendant's motion to exclude the testimony of Dr. Najjar under *Daubert*.

Dr. Najjar's expert opinion is admissible for purposes of summary judgment, and Dr. Najjar has opined that Mr. Napolitano suffered from bisphosphonate-induced osteonecrosis of the jaw ("BONJ") like lesions in his right mandible, which manifest after Mr. Napolitano began receiving Zometa infusions. Najjar Report (Ex. 5 to Docket No. 2505). In rebuttal, Dr. Najjar stated that Mr.

Napolitano met the AAOMS<sup>1</sup> definition of BONJ. Najjar Rebuttal Report (Ex. 6 to Docket No. 2505); *see also* Najjar Deposition (Ex. 7 to Docket No. 2505, pp. 116-117).

Defendant's attacks on Dr. Najjar's opinion go to the credibility and accuracy of that opinion, but for purposes of summary judgment, Plaintiff has carried her burden. Defendant's motion on this issue is denied.

FAILURE TO WARN  
(STRICT LIABILITY AND NEGLIGENCE)

Regardless of the descriptive terminology used to denominate the cause of action, where the theory of liability is failure to warn, negligence and strict liability are equivalent under New York law. *Wolfgruber v. Upjohn Co.*, 423 N.Y.S.2d 95, 97 (N.Y. App. Div. 1979). Whether an action is pleaded in strict products liability, breach of warranty or negligence, it is the plaintiff's burden to show that a defect in the product was a substantial factor in causing the injury and that the defect complained of existed at the time the product left the manufacturer. *Tardella v. RJR Nabisco, Inc.*, 576 N.Y.S.2d 965, 966 (N.Y. App. Div. 1991).

To succeed on a failure to warn claim, plaintiffs are required to prove that the product did not contain adequate warning and that the inadequacy of the warnings was the proximate cause of the injury. *Mulhall v. Hannafin*, 841 N.Y.2d 282, 285 (N.Y. App. Div. 2007). The manufacturer's duty, under New York law, is to warn the medical community, not the patient, of the product's risk. *Id.*<sup>2</sup>

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<sup>1</sup> American Association of Oral and Maxillofacial Surgeons

<sup>2</sup> Under this "informed intermediary doctrine," the manufacturer of a prescription drug has a duty to warn of all potential dangers which it knows or should know and must take such steps as are reasonably necessary to bring that knowledge to the attention of the medical profession. *Figueroa v. Boston Scientific Corp.*, 254 F.Supp.2d 361, 370 (S.D. N.Y. 2003).

Defendant argues that its warnings were adequate, for the reasons stated in its Motion for Summary Judgment on the Adequacy of its Aredia and Zometa Warnings. The Court has found that there are genuine issues of material fact as to the adequacy of Defendant's warnings and denied that Motion. "Generally, whether a warning is adequate is an issue of fact to be determined at trial." *Figueroa v. Boston Scientific Corp.*, 254 F.Supp.2d 361, 370 (S.D. N.Y. 2003).

To establish her failure to warn claim, Plaintiff also has the burden to show that had a different warning been given, this patient would not have used the product that caused her injury. *Mulhall*, 841 N.Y.S.2d at 287. The *Mulhall* court stated that, in that case, the plaintiff had to show that, had the warning been different, the doctor would have departed from her normal practice and used another product. *Id.*<sup>3</sup>

It remains Plaintiff's burden to prove that defendant's failure to warn was a proximate cause of her injury, and this burden includes adducing proof that the user of a product would have read and heeded a warning had one been given. *Sosna v. American Home Products*, 748 N.Y.S.2d 548, 549 (N.Y. App. Div. 2002). To constitute proximate cause, an inadequate warning must be a substantial cause of the events leading to the injury. *Figueroa*, 254 F.Supp.2d at 370. Plaintiffs need not positively exclude every other possible cause; rather, the proof must render those other causes sufficiently remote or technical to enable a jury to reach its verdict based not upon speculation, but

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<sup>3</sup> In *Mulhall*, which involved a medical device, the doctor had testified that she selected the product over all other available devices because she had used it safely in her practice since 1992 and the medical literature had documented that it performed well without side effects. *Mulhall*, 841 N.Y.S.2d at 287.

upon the logical inferences to be drawn from the evidence. *Gayle v. City of New York*, 703 N.E.2d 758, 759 (N.Y. 1998).<sup>4</sup>

Plaintiff has presented evidence that Dr. Kessler, his dentist, would have changed his handling of Mr. Napolitano's treatment had he known of the information in Defendant's "Dear Doctor" letter, which he never saw. Kessler Deposition (Docket No. 2612-4), p. 144. Dr. Kessler further stated that, based upon what he now knows with regard to Zometa treatment and ONJ, it would be his practice to speak with the oncologist of a person receiving Zometa prior to giving them dental treatment. *Id.* at 159.

Dr. Chachoua, Mr. Napolitano's oncologist, testified that he stopped Mr. Napolitano's Zometa when he began to suspect the ONJ was related. Chachoua Deposition (Docket No. 2612-2), pp. 117, 129. Dr. Chachoua now discusses with his patients the risk of ONJ and possible linkage of ONJ to Zometa at the very beginning of treatment. *Id.* at 180. He asks the patient to consult with a dentist to get their teeth evaluated and report any jaw pain they may have during treatment. *Id.* at 180-81. He also testified, "Since the work in ONJ has been reported, one is much more aware of the risks, and so if there's any dental issues, then we tend not to prescribe the drug. *Id.* at 87.<sup>5</sup>

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<sup>4</sup> In *Hoffman-Rattet v. Ortho Pharmaceutical Corp.*, 516 N.Y.S. 2d 856 (N.Y. Sup. Ct. 1987), the court held that, once a patient establishes that an inadequate warning has been given, a presumption arises that the inadequacy was a proximate cause of the pharmaceutical item in question having been prescribed or continued. *Id.* at 861. This presumption may then be rebutted by affirmative evidence introduced by the defendant showing that even if adequately informed, the physician would still have prescribed the item. *Id.*; see also *Anderson v. Hedstrom Corp.*, 76 F.Supp.2d 422, 441 (S.D. N.Y. 1999). In this case, however, the Court has found that, for purposes of summary judgment, there are questions of fact as to the adequacy of Defendant's warnings, so the burden has not shifted to Defendant.

<sup>5</sup> Defendant's assertion that Dr. Chachoua testified that he would have still prescribed Zometa to Mr. Napolitano in November of 2004, even if he had been aware of the potential ONJ risk

Defendant's arguments go to the credibility and weight to be given this testimony. Plaintiff has sufficiently established genuine issues of material fact as to whether different warnings would have made a difference in the behavior of Mr. Napolitano or his treating physicians; that is, whether Defendant's failure to warn was a proximate cause of Mr. Napolitano's injury. Defendant's Motion for Summary Judgment on this issue is denied.

#### EXPRESS WARRANTY

An express warranty, under New York law, is an "affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain." *Horowitz v. Stryker Corp.*, 613 F.Supp.2d 271, 286 (E.D. N.Y. 2009). An action for breach of express warranty requires both the existence of an express promise or representation and reliance on that promise or representation. *Id.*

Plaintiff has not responded to Defendant's arguments concerning the breach of express warranty claim. *See* Docket No. 2610. In addition, Plaintiff has not presented evidence that Defendant made any express warranty in this case or that Mr. Napolitano or his physicians relied upon such warranty. Therefore, Defendant's Motion for Summary Judgment on Plaintiff's breach of express warranty claim is granted, and that claim is dismissed.

#### IMPLIED WARRANTY

Plaintiff's implied warranty claim is also based upon the alleged failure to warn. For the same reasons summary judgment is denied on Plaintiff's failure to warn (strict liability and

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at that time, is not supported by its citations to the record.

negligence) claims, there are genuine issues of material fact which preclude summary judgment on the breach of implied warranty claim as well. Therefore, Defendant's Motion for Summary Judgment on this claim is denied.

#### LOSS OF CONSORTIUM

Plaintiff's loss of consortium claim derives from and is dependent upon Plaintiff's other claims. Therefore, Defendant's Motion for Summary Judgment on this claim is denied.

IT IS SO ORDERED.

  
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TODD J. CAMPBELL  
UNITED STATES DISTRICT JUDGE